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APR - 7 1994

Edward T. Lentz  
Corporate Patents U.S. - UW2220  
SmithKline Beecham Corporation  
P.O. Box 1539  
King of Prussia, PA 19406 - 0939

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,721,723

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,721,723 issued January 26, 1988, which claims the human drug product Paxil, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 702 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 23, 1993. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (667) + 1,135 \\ &= 1,469 \text{ days}\end{aligned}$$

Since the regulatory review period began January 21, 1984, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on January 21, 1984, up to the issuance of the patent on January 26, 1988, is 1,465 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $2,132 - 1,465 = 667$  days. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (December 29, 1992) when added to the period of extension calculated above (1,469 days) cannot exceed fourteen years. The period of extension is thus limited to December 29, 2006, by operation of 35 USC § 156(c)(3). Since the patent term of seventeen years (35 USC § 154) would expire on January 26, 2005, the period of extension is the number of days to extend the term of the patent from its expiration date to and including December 29, 2006, or 702 days.

The limitations of 35 USC § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,721,723 a certificate of extension, under seal, for a period of 702 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,721,723
Granted:	January 26, 1988
Applicant:	Roger D. Barnes et al.
Owner of Record:	Beecham Group p.l.c.
Title:	ANTI-DEPRESSANT CRYSTALLINE PAROXETINE HYDROCHLORIDE HEMIHYDRATE
Classification:	514/321
Product Trade Name:	Paxil
Term Extended:	702 days

*C.E. Van Horn*

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Charles E. Van Horn  
Patent Policy & Projects Administrator  
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 11-44  
Rockville, MD 20857

RE: Paxil

FDA Docket No.: 93E - 0146